Medical Recording Tools for Biodosimetry in Radiation Incidents

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ABSTRACT

NATO Standardization Agreement (STANAG) 2474, entitled "Determination and Recording of Ionizing Radiation Exposure For Medical Purposes," calls for thorough medical recording in radiation exposure incidents. There are also U.S. Specific Military Requirements (SMR) to "Identify or develop and validate viable low-cost field biodosimetry" (FY01/02), on converting the "Biological Assessment Tool" (BAT) to a hand-held computer device (FY03/04), and "Field Radiological Biodosimetry" (FY05/06). BAT output has been accepted as a requirement for the Theater Functional Working Group Integrated Process Team (TFWG IPT) for incorporation into deployment medical database, and has been used in radiological exercises. To meet all these requirements, the Armed Forces Radiobiology Research Institute (AFRRI) has prepared a CD-ROM package entitled "Radiation Biological Dosimetry Tools for Emergency Responders." This collection includes three subsets of medical assistance tools: 1. Casualty Management Guidance includes the "Terrorism with Ionizing Radiation Guidance Pocket Guide" and the "Medical Management of Radiological Casualties Handbook," both of which were previously available in hard copy and can now be downloaded as PDF (portable document format) files from the CD-ROM. 2. Medical Data Forms include AFRRI adaptations and expansions of previous military forms to include applicability to civilians and youth. The "AFRRI Adult/Pediatric Field Medical Record" was adapted from the U.S. Army's Field Medical Card. The "AFRRI Biodosimetry Worksheet" was adapted from the NATO STANAG 2474 Appendix 1, "Medical Record of Ionising Radiation Dose and Contamination." 3. Exposure Assessment Software includes the BAT, which was developed by AFRRI in collaboration with the Radiation Emergency Assistance Center/Training Site (REAC/TS) for recording diagnostic information in suspected radiological exposures. BAT version 0.75 is currently available also at the website www.afrri.usuhs.mil, and version 1.0 is nearing completion. The BAT output reports meet the requirements of NATO STANAG 2474. The "First-responders Radiological Assessment Triage" or FRAT is similar to the BAT but for use on hand-held personal digital assistant devices. It was not available for inclusion in the first CD-ROM but will be completed for the second edition. FRAT will provide data-collection templates for analysis of clinical signs and symptoms, lymphocyte counts, physical dosimetry, radioactivity, and location-based dose estimates. FRAT will then compare this data with known radiation dose responses to provide "triage" dose assessments and estimates of hospitalization and mortality outcomes. The first edition AFRRI CD-ROM will be distributed by the U.S. Department of Homeland Security's Emergency Response Technology Program. Over the expected three-year duration of the NATO RTG-099, the tools from this CD-ROM will be updated and expanded, and new ones created. For example, the next-generation BAT after version 1.0 is planned to incorporate medical treatment guides covering the use of antibiotics, cy-

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1.0 INTRODUCTION

NATO in general, and the U.S. military in particular, have recognized the need for improved medical recording tools in radiation-exposure incidents. Imagine, if you will, a mass-casualty radiological accident or terrorist attack. First responders flood into the scene and try to cope with perhaps dozens, hundreds, or even thousands of obvious casualties along with a throng of dazed psychological casualties who may or may not have suffered radiation exposure or even still bear radioactive contamination on or in their bodies. The first responders' best efforts to triage and treat this mass of people will be hampered severely if they lack proper medical recording tools. Thorough recording allows for better tracking of patients through the medical system and maximizes the opportunities for long-term follow-up, both for treatment of the individuals and for research on the short- and long-term effects of radiation exposure.

Therefore, for instance, NATO Standardization Agreement (STANAG) 2474 NBC/MED, entitled "Determination and Recording of Ionizing Radiation Exposure for Medical Purposes," calls for complete recording of medical data of all victims in radiation-exposure incidents. Specifically, the stated goal of STANAG 2474 reads as follows, "The aim of this agreement is to ensure that operationally incurred ionizing radiation doses, estimated or measured, of all those presenting, whether as outpatients or inpatients, at medical facilities, are obtained and recorded, or measures taken for subsequent determination and recording, in appropriate medical records, so that medical management may be optimized and full and permanent records created." This STANAG refers to both physical dosimetry, or the use of instruments to measure radiation dose, biodosimetry, the use of medical indicators to predict dose, as well as dose reconstruction, which is applying dose zone information to the people known to be in that area.

Also, there have been, over the years, many U.S. Specific Military Requirements (SMRs) that speak to these issues. For instance, one SMR in FY01/02 was to "Identify or develop and validate viable low-cost field biodosimetry," which was achieved by the development at AFRRI of the Biodosimetry Assessment Tool or BAT.[Sine *et al.*, 2000; Salter *et al.*, 2004] In FY03/04, another SMR was on converting the "Biological assessment tool" to a hand-held computer device, which became the First-responders Radiological Assessment Triage or FRAT. The SMR on "Field Radiological Biodosimetry" for FY04/05 is of greatest relevance to the RTG-099's future efforts. It states that:

> "Biological radiation dose assessment requires three areas of research and development: (i) A blood-based field biodosimetry assay system using commercial-off-the-shelf equipment adapted for deployable military laboratories with dual-use NBC medical diagnostic applications. A low-cost blood cell counter has been successfully field tested, but it requires the development of either a validated human radiation calibration curve for lymphocytes and monocytes or a method to deplete monocytes. Blood-based radiation responsive molecular biomarkers have been identified, which can be detected in real time in military field labs, but this approach needs to be further optimized and validated. (ii) The current test version of Biological Assessment Tool (BAT) used for dose estimation and triage runs on a personal computer platform using Windows operating system. BAT needs to be transitioned to a hand-held (e.g., Palm Pilot) system for portability and field use. (iii) A clinical-based biodosimetry system will provide physicians the ability to triage radiation victims, make treatment decisions, reduce uncertainties on individual response to radiation exposure, and help estimate individual doses."

Part (i) of this SMR will be covered in other presentations at the RTG-099 June 21-23, 2005 meeting, but this paper will continue to discuss parts (ii) and (iii).

Such records require far more than simply writing down on paper the patient's presenting symptoms. Tools are required that allow an estimation of radiation dose by scientific inference from these signs and symptoms. They also will facilitate differentiation between truly exposed individuals and the unexposed but concerned public to maximize efficient use of constrained medical resources. And this is where the Armed Forces Radiobiology Research Institute's (AFRRI) efforts to create such tools come into play. The BAT has been accepted as a requirement for the Theater Functional Working Group Integrated Process Team (TFWG IPT) for incorporation into its deployment medical database. It has also been used in radiological exercises such as TOPOFF (Top Officials) anti-terrorism exercises.

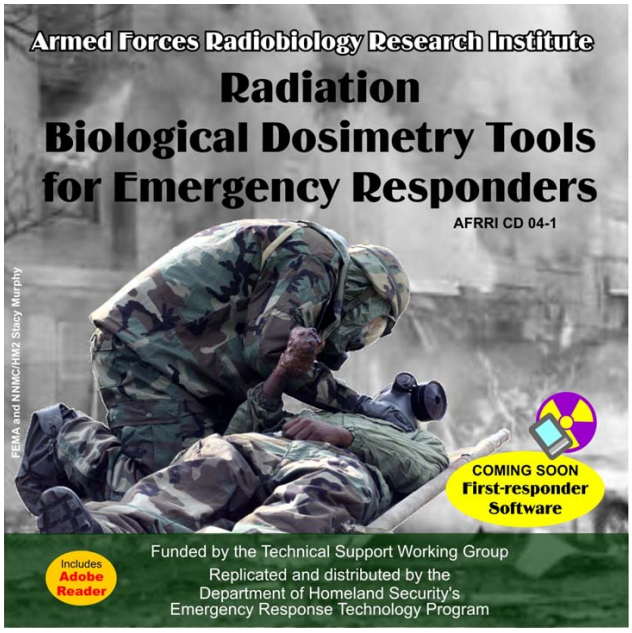

Figure 1: Cover of AFRRI's CD-ROM

2.0 A NEW CD-ROM OF BIODOSIMETRY TOOLS

To meet all the above NATO and U.S. SMR needs, AFRRI has developed a new CD-ROM entitled, "Radiation Biological Dosimetry Tools for Emergency Responders." Development of this package of tools was funded by the Technical Support Working Group. Replication and distribution of the CD-ROM is being handled by the Department of Homeland Security's Emergency Response Technology Program. This first CD-ROM contains three subsets of tools—guidance for managing casualties, forms for recording medical information, and software tools for assessing exposure doses. The CD-ROM promises more tools for the next edition.

Figure 2: The CD-ROM's main screen

2.1 Casualty Management Guidance

The CD-ROM begins by emphasizing what treatment providers should do in the medical management of casualties. There are two different tools in this first subset, one a complete handbook, and the other an abbreviated summary for quick reference and a brief overview.

2.1.1 Terrorism with Ionizing Radiation Guidance Pocket Guide

This provides information for dealing with terrorism involving ionizing radiation. It includes such topics as diagnosis, treatment considerations, decontamination procedures, and public health reporting procedures. This document was originally developed by the U.S. Department of Veterans Affairs as a two-page pocket guide available in printed form and via the internet (currently available at the AFRRI website www.afrri.usuhs.mil). It was designed for emergency situations in which a quick response was essential to assess and control the situation.

2.1.2 Medical Management of Radiological Casualties Handbook

AFRRI had earlier developed a printed form of this handbook, representing the 2nd edition guidance doctrine. It provides concise supplemental reading material for the AFRRI Medical Effects of Ionizing Radiation (MEIR) Course and helps prepare medical-care providers to treat injuries complicated by ionizing radiation exposure and radioactive contamination.

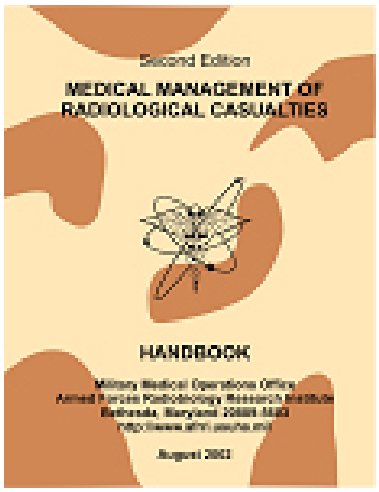

Figure 3: Medical Management Handbook

The handbook also is available for download via the internet at the AFRRI website, or it can be downloaded or even printed from the CD-ROM. The first version of the CD-ROM also promises that future editions will include this same handbook in a form downloadable to Palm PDA (personal digital assistant) devices. To accomplish this, the second edition of the AFRRI handbook will be redesigned, using Adobe FrameMaker desktop publishing software. Portions of the text will require extensive format changes and/or will be condensed for the Palm screen size.

2.2 Medical Data Forms

The second subset of biodosimetry tools on the CD-ROM deals with the actual recording of medical data relevant to radioactive contamination, exposure, and resulting patient symptoms. There are two different tools included, one a brief field record, and the other a more comprehensive worksheet.

2.2.1 AFRRI Adult/Pediatric Field Medical Record

This is a convenient one-page form for recording emergency medical information in the field. It was adapted from the U.S. Army's Field Medical Card into an electronic form applicable both to military personnel and civilians, both to adult and pediatric cases. For instance, it has an adult body map and also a pediatric body map for labeling areas of contamination or injury. It also includes sections on personal data, types of injury, other symptoms, treatments administered, and disposition of the case.

Figure 4: U.S. Army Field Medical Card

2.2.2 AFRRI Biodosimetry Worksheet

This provides a four-page data entry worksheet for gathering facts about a case of radiation exposure, including the source and type of radiation, the extent of exposure, and the nature of the resulting injuries. It also is applicable to both adult and pediatric cases. This worksheet was adapted by AFRRI from the NATO STANAG 2474 Appendix 1, "Medical Record of Ionising Radiation Dose and Contamination." It includes the basic items from the one-page Field Medical Record, and quite a bit more as well. Additional features include a detailed section on types of radiation sources present, radioactive exposure, external and internal contamination, and consequent symptoms. There are two sets of adult and pediatric body maps, one for contamination distribution and the other for estimated dose distribution. There is a section for tracking changes in counts over time of various blood cell lines. Finally, there is an entire page for additional notes and comments. Information on this Biodosimetry Worksheet can be used to complete many sections of the BAT software program.

2.3 Exposure Assessment Software

This first edition of the CD-ROM includes one complete software program and states that a second will be available for the next edition.

2.3.1 Biodosimetry Assessment Tool (BAT)

The BAT software program was developed by AFRRI in collaboration with the Radiation Emergency Assistance Center/Training Site (REAC/TS) for recording diagnostic information in suspected radiological exposures. Version 0.75 is included on the CD-ROM and also is available on the AFRRI www.afrri.usuhs.mil for direct download. The minimum system requirements are: Windows 9x, ME, NT, 2000 or XP operating systems and a Pentium 200 with 128 MB of RAM and 10 MB of free disk space.

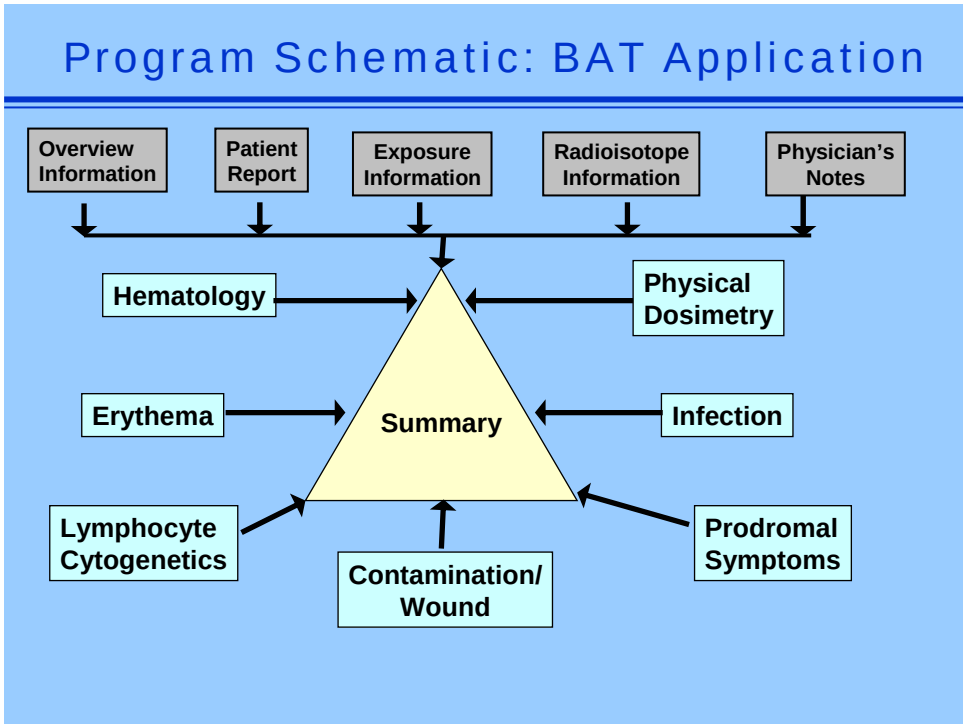

Figure 5: BAT schematic plan

The BAT software application equips healthcare providers with diagnostic information (e.g., physical dosimetry and clinical signs and symptoms) germane to the management of human radiation casualties. Designed primarily for prompt use after a radiation incident, the user-friendly program facilitates collection, integration, and archiving of data obtained from exposed persons. Data collected in templates are compared with established radiation dose responses obtained from the literature to provide multi-parameter dose assessments. The program archives clinical information (e.g., extent of contamination, wounds, and infection) that is useful for casualty management, displays relevant diagnostic information in a concise format, and can be used to manage both military and civilian radiation accidents. In addition, the use of this program to monitor individual patient diagnostic information could minimize the severity of psychological casualties by making a marked impact on the way that radiation casualties and the worried well view their exposure, dose, and future risk for the development of disease.

Figure 5 shows a schematic outline of the BAT program's structure. Background information about the patient and the circumstances of the suspected radiological incident are entered first (see, for example, Figure 6). Then medical data on various symptom categories are entered next. See Figure 7 for the main symptom-entry screen, with tabs that go to each of the symptom categories. Only the categories for which data are available would be used for a given patient. In some cases, that may mean only 2 or 3 sections would be used, and the other tabs could be ignored.

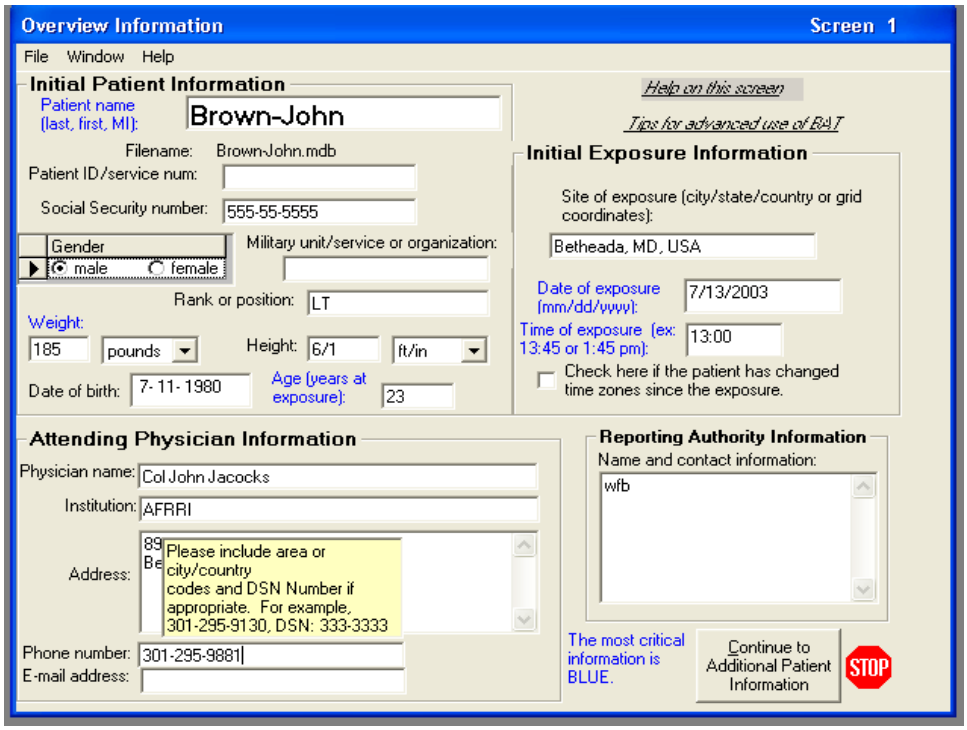

Figure 6: Personal-data entry screen

While all the symptom categories for which data are available would be useful in treating a patient, two are of special relevance to estimating dose received. These are latency to vomiting in the prodromal symptoms category (see Figures 8.a and 8.b), and the absolute number of lymphocytes in the hematology category (see Figure 9) [Anno *et al.*, 1989; Goans *et al.*, 1997; Goans *et al.*, 2001; Guskova *et al.*, 2001].

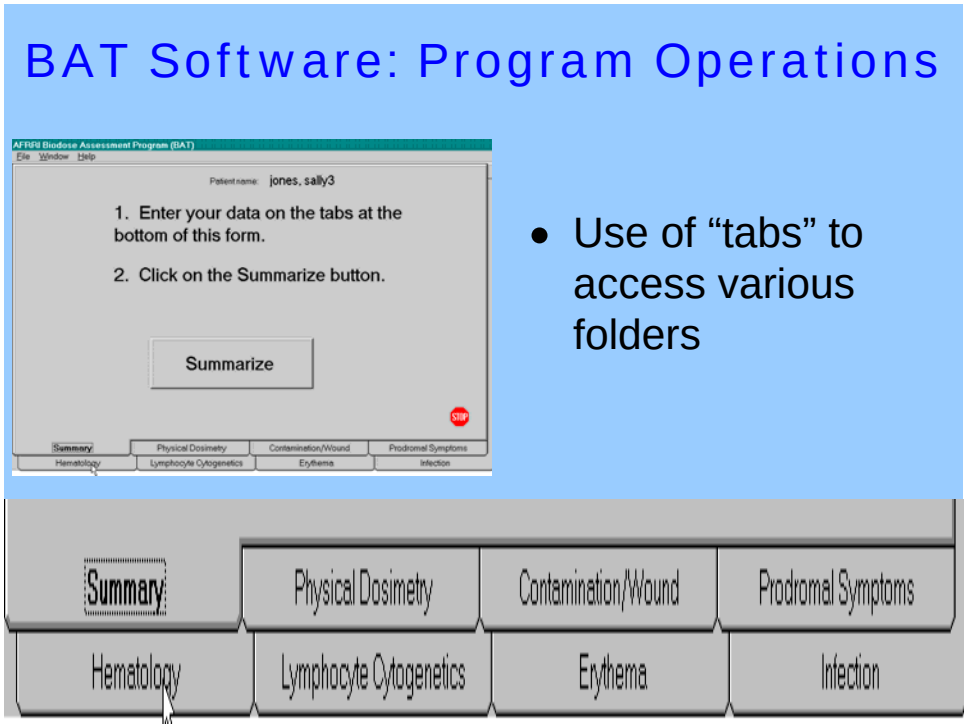

Figure 7: Master screen for symptom entry

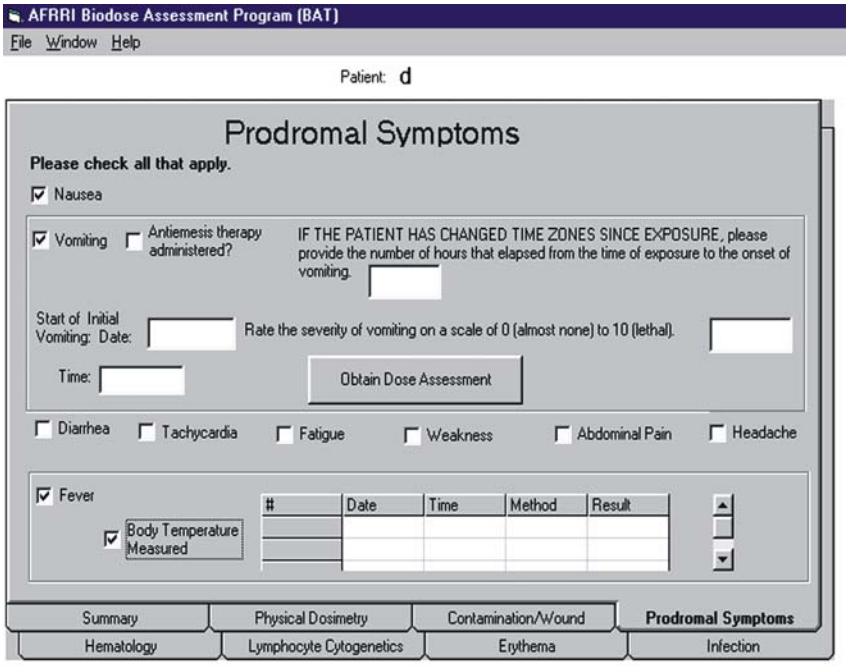

Figure 8.a: Vomiting input screen

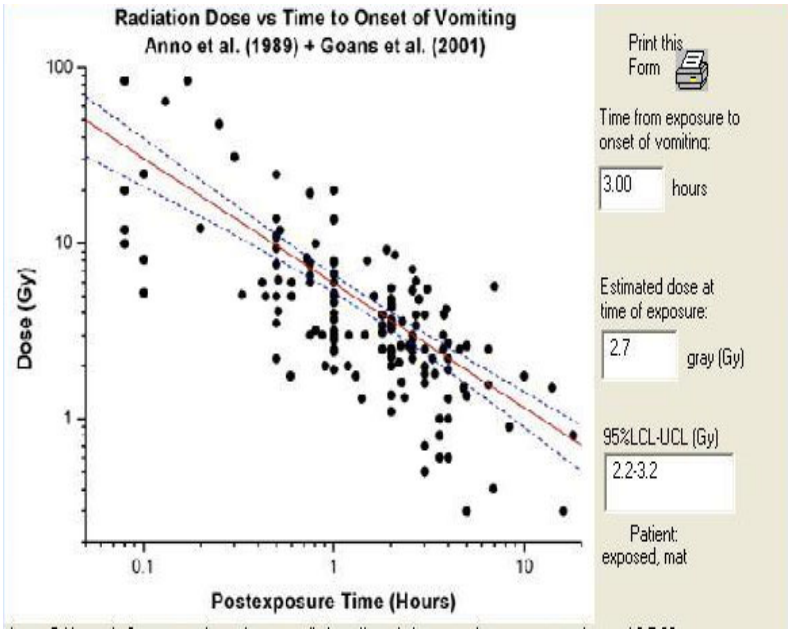

Figure 8.b: Onset to vomiting as an indicator of radiation dose

Figure 8.a shows the screen where vomiting data can be entered, while Figure 8.b shows the scientific data correlating known dose with latency to vomiting, such that latency in a future incident can be used to estimate dose.

Similarly, Figure 9 shows the hematology data-entry screen, which has room for up to 13 serial measures of lymphocytes over time. And Figure 10 shows the previous medical data with known doses so that dose can be estimated in the future based on lymphocyte counts. Note in Figure 9 that dose can be estimated from a single lymphocyte count simply by clicking on the "SHOW DOSE" button after entering the number. A better estimate, however, can be derived from lymphocyte kinetics showing changes over time as revealed by multiple measures. All one need do is click on "GET MULTI-SAMPLE DOSE ESTIMATE." Figure 11 shows an example of the kind of feedback screen one would get in response. While other patient data like cytogenetics can be used to calculate dose later, the advantage of these two symptoms is that the physician or other user of the BAT program can get immediate feedback on estimated dose, bound by error bars or upper and lower confidence limits (UCL and LCL, respectively).

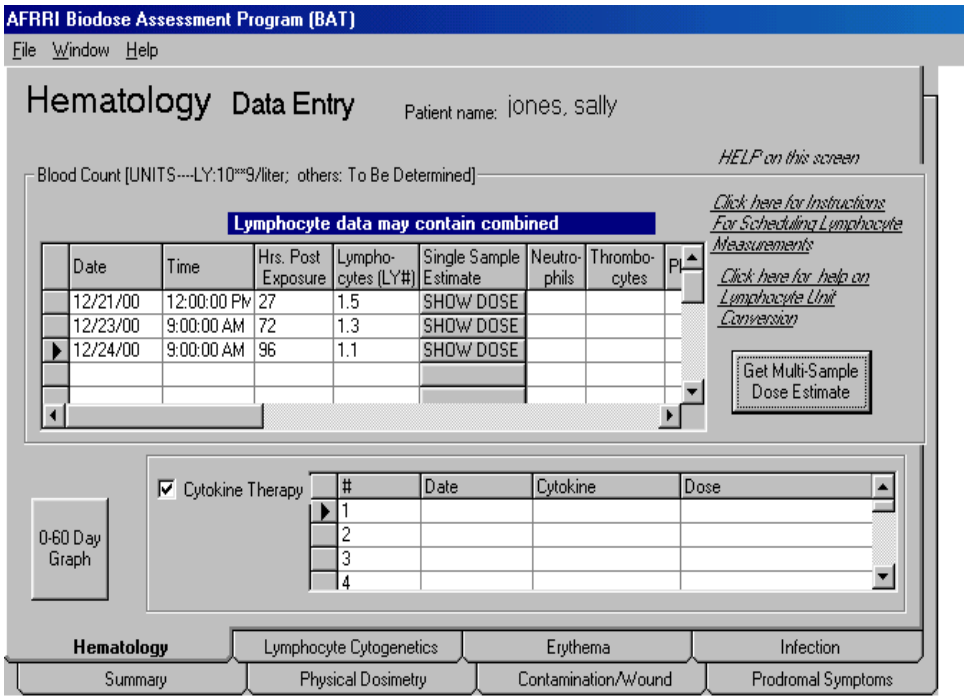

Figure 9: Hematology data-entry screen

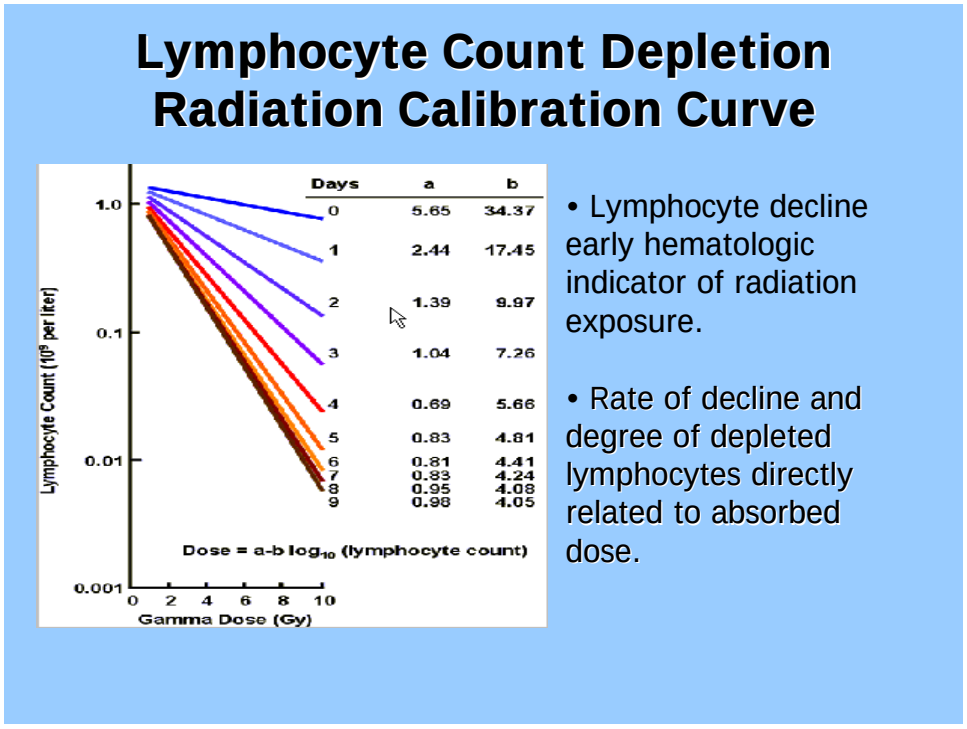

Figure 10: Lymphocyte depletion kinetics and radiation dose

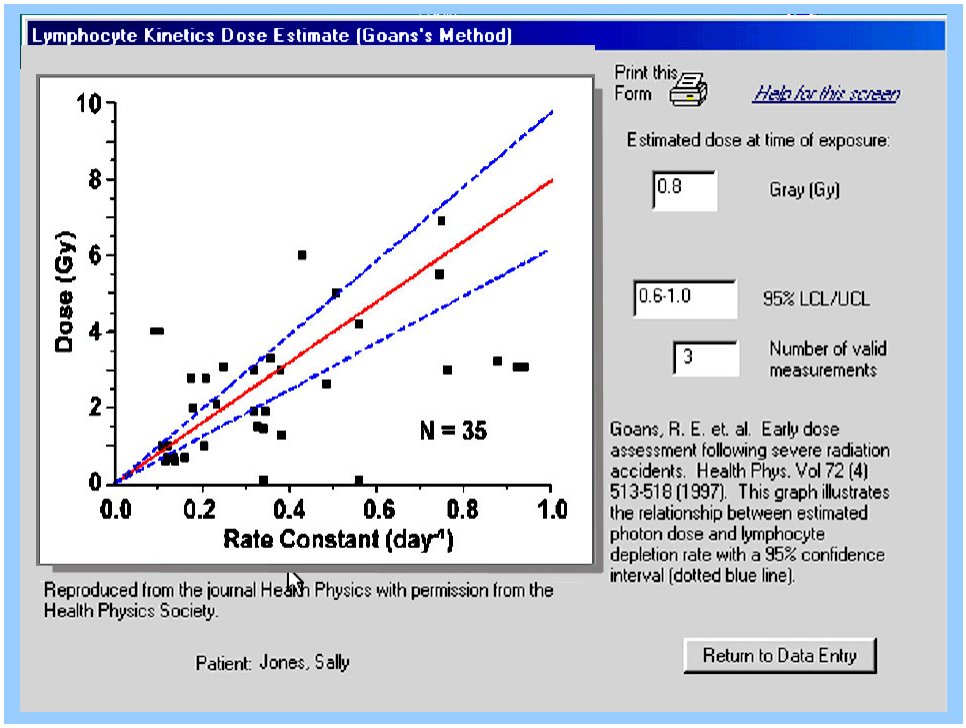

Figure 11: A sample dose-estimate screen

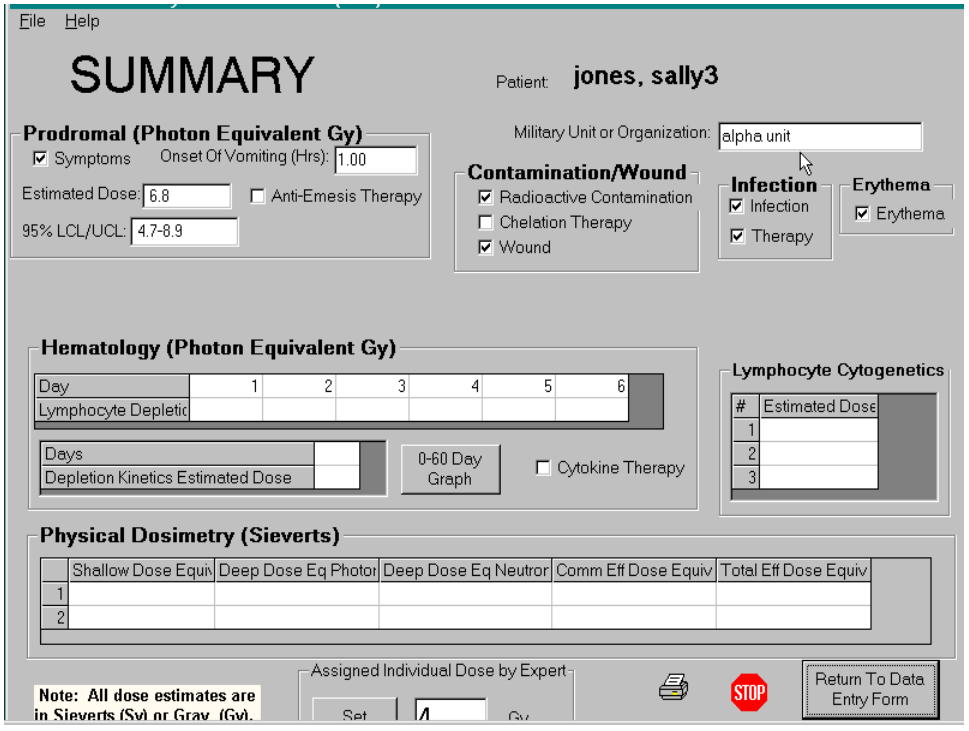

Figure 12: Summary screen

Figure 12 shows the BAT summary screen that capsulizes all the most relevant information entered or computed earlier for the given patient. The various symptom categories present are displayed, along with information on dose estimates. Note in this example that dose was estimated by onset of vomiting but not by hematology or cytogenetics. If such information or additional diagnostic indices became available later, of course, the operator could add that at any time.

BAT Version 0.75 was used in the first edition of the CD-ROM, and Version 1.0 was not completed until later. Enhancements in the newer version include a calendar format change to circumvent an XP Office software bug, an additional "help" screen, updated lists of known users, and addition of the "Terrorism with Ionizing Radiation Guidance Pocket Guide."

2.3.2 First-responders Radiological Assessment Triage (FRAT) Software

FRAT was not yet complete when the first edition of the CD-ROM was produced, though the latter did promise it would be available later. While the two systems are somewhat related, BAT requires a desktop or laptop computer, while FRAT works on a hand-held device such as the Palm PDA. BAT computers could be used in a far-forward command post, such as those shown in Figure 13, but the size and portability of FRAT make it ideal for first-responders or any others who will enter a radiological incident zone and need to make patient data entry or dose estimates while operations are underway.

Figure 13: Forward computer assets for BAT

The FRAT software application allows first responders to triage suspected radiation casualties based on the initial or prodromal features as listed in the VA's Terrorism with Ionizing Radiation General Guidance Pocket Guide. FRAT was developed initially to use the Palm operating system for portability on PDA devices by using Mobile VB, a Microsoft Visual Basic add-on. The FORTRAN program was converted and integrated into

the application. The device-specific PDA Runtime tool, which can be downloaded from the AppForge website (www.appforge.com), must be loaded along with the FRAT application on a PDA device.

The FRAT program permits convenient entry of (1) signs and symptoms, (2) blood lymphocyte counts, and (3) dosimetry data, all with minimum text entry requirements. See Figure 14 for a schematic of possible inputs to FRAT. As with BAT, only the program components for which data are available are used. Otherwise, they can be ignored until such time as pertinent data are gathered.

For some sample input screens, see Figure 15. At the center is the main input screen, with links to the same three subsections mentioned above. The upper left shows the principal signs and symptoms screen, with the same nine as indicated in the previous figure. Because one of the most important symptoms for dose estimation is vomiting, if one touches the PDA screen with a stylus, he reaches the upper right screen on Figure 15.

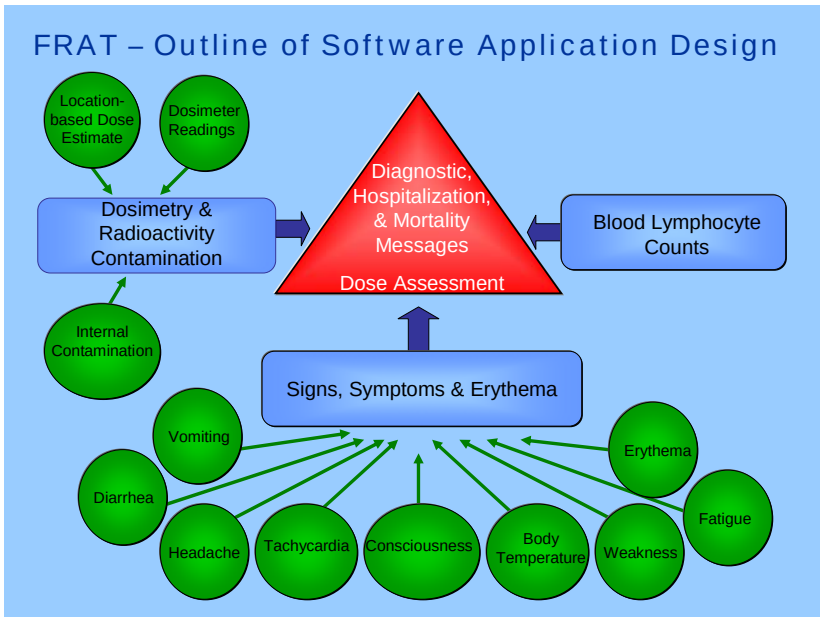

Figure 14: Schematic outline of FRAT

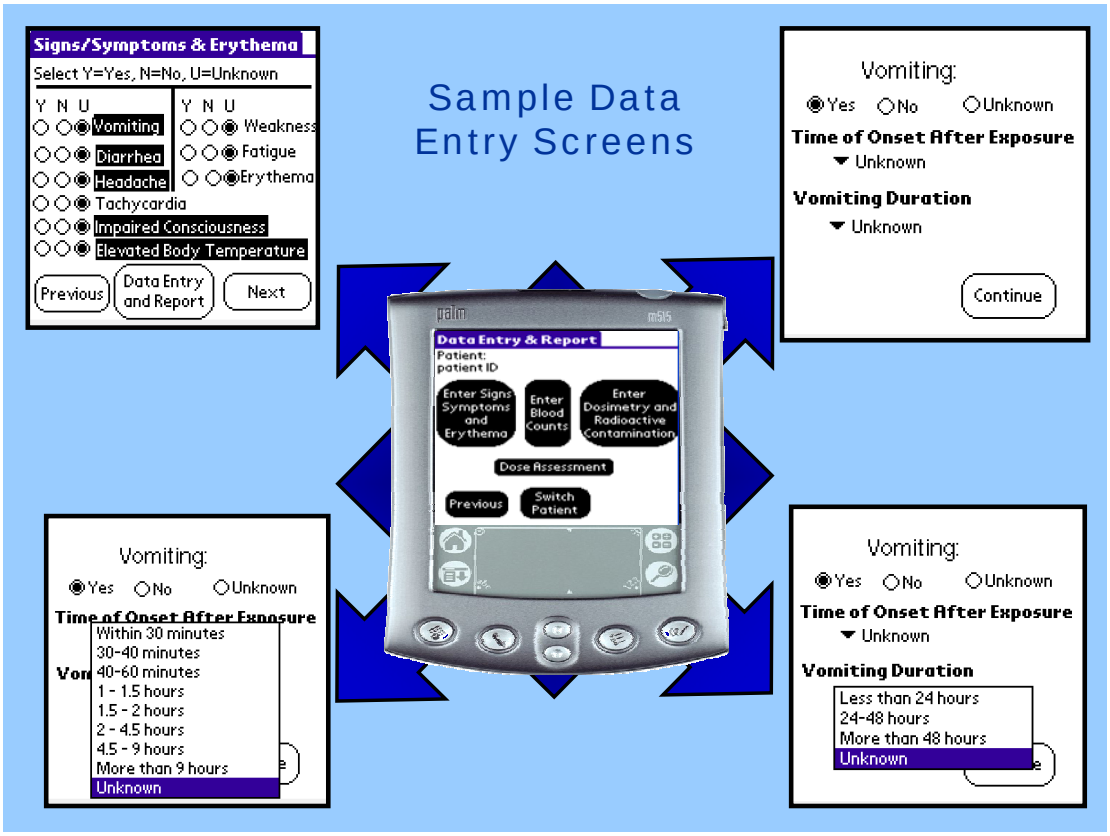

Figure 15: Sample FRAT entry screens

If “continue” is touched, one proceeds to time of onset after exposure, in the lower-left screen, and then vomiting duration in the lower-right screen. The other signs and symptoms have similar screens. Note that no writing is required for most data entry—in most cases the options are built in and one must simply touch the various screens with a stylus to proceed. Once familiarity with the program has been achieved, it is possible to enter all the known facts about a given case quite rapidly.

A panel of experts in radiobiology and the medical effects of ionizing radiation (Table 1) was administered a questionnaire asking them to provide their judgments about the possible contributions of each diagnostic factor mentioned above to predict radiation dose received. First, they were asked to estimate how useful each factor would be in predicting whether or not radiation exposure had occurred at all. Then they were asked to rate how reliable that factor might be in estimating the dose if exposure had occurred. Answers were to be provided with a 100 point scale where zero meant the item had no value in such judgments. Ratings on each item were ranked and then the median score was used to weight each sign and symptom factor in the multi-parameter-based determination of a triage dose.

Table 1: Medical and radiobiology experts consulted regarding the appropriate weights to assign each dose predictive factor in AFRRI's First-responders Radiological Assessment Triage (FRAT) software

FRAT Expert Panel

George H. Anno, Ph.D. (Pacific-Sierra Research Corp.)	William F. Blakely, Ph.D. (AFRRI)	Elena Buglova, M.D. (IAEA)
Nicholas Dainiak, M.D. (Bridgeport Hospital)	William E. Dickerson, M.D. (AFRRI)	David Holt, Ph.D. (Institute of Naval Medicine, United Kingdom)
John Jacocks, M.D. (Army Test and Evaluation Command)	Pataje G.S. Prasanna, Ph.D. (AFRRI)	Charles A. Salter, Ph.D. (AFRRI)
Vijay K. Singh, Ph.D. (AFRRI)	Horace Tsu, M.D. (AFRRI)	Govert P. van der Schans (The Netherlands Organization for Applied Scientific Research, Prins Maurits Laboratory)

At the conclusion of data entry, one need but touch the stylus to "Dose Assessment" on the main screen to get immediate feedback in the form of several informational output screens to advise the first responder about triage and prognosis on the case (see Figure 16). The screen in the upper left advises whether the patient has received no dose, been exposed but with no estimation of the magnitude of dose being possible, or a specific degree of overexposure. The screen in the upper right then provides a dose estimate (if possible) in centi-Gray (cGy), along with confidence limits. Next comes the screen in the lower left, which addresses reliability and diagnostic information. Finally the screen in the lower right of Figure 16 reports hospitalization estimations and mortality projections. All this information has great utility for triage as well as treatment.

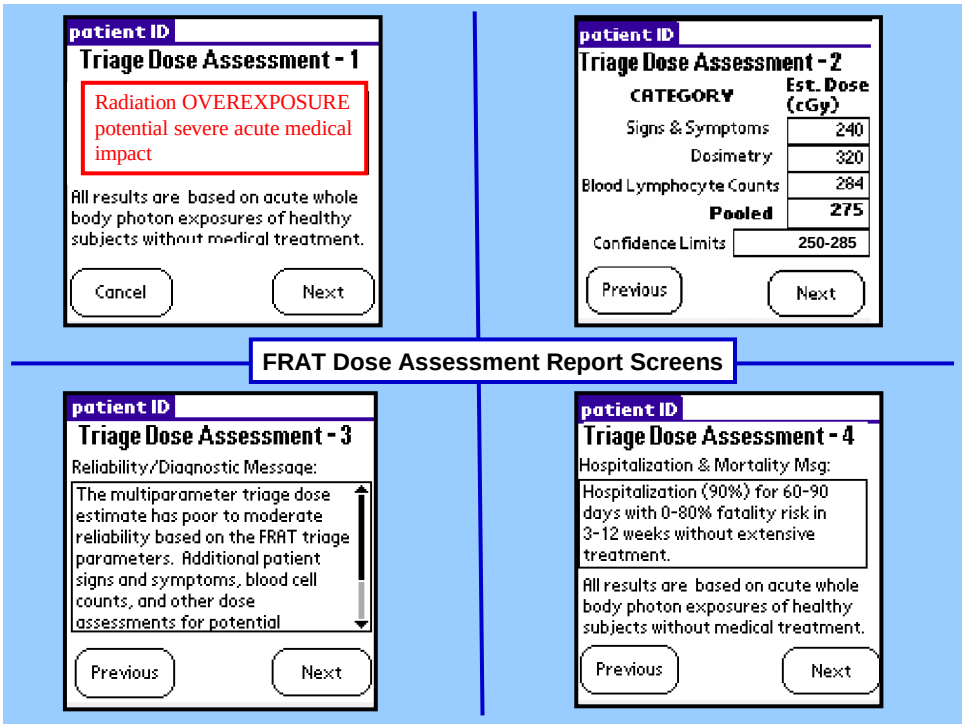

Figure 16: FRAT output screens

3.0 FUTURE RESEARCH ON BIODOSIMETRY TOOLS

It is expected that during the three-year life of the NATO RTG 099 additional biodosimetry tools will be developed as well as revisions and expansions of the current tools already discussed. Members of the NATO RTG are invited to collaborate in this work.

3.1 Revision and Expansion of Existing Tools

The second edition of the AFRRI Medical Management of Radiological Casualties Handbook will be redesigned for display on hand-held computer devices, using Adobe FrameMaker desktop publishing software. Portions of the text will require extensive format changes and/or will be condensed for the smaller screen size, converted to a file format, viewable when installed on Palm-type PDAs and possibly pocket PCs. AFRRI's two-page pocket guide, "Terrorism with Ionizing Radiation General Guidance," also will be converted for PDA use.

Expanded versions of BAT and FRAT will be developed. For instance, the next generation BAT will incorporate medical treatment guides covering the use of antibiotics, cytokines, and decorporation therapy. BAT and FRAT also will be converted to forms that can be integrated with and run on third-party commercial emergency-response software applications. This will require porting the existing products to such systems as the Windows PC OS, Windows CE or Windows for Pocket PC OS, and to the Palm OS or other PDA OS having significant market share.

It is hoped also that BAT and FRAT can be integrated with other, more universally applicable military medical data-recording systems, such as the Battlefield Medical Information System-Tactical or BMIST [Martinez-Lopez 2004].

3.2 Emerging Biodosimetry Tools

Vomiting and hematology are not the only medical signs that might be of use in estimating dose. See Figure 17 for other biomarkers that could be investigated for this purpose. Reliability and validity of the equipment under field conditions will need to be explored, and solid dose-response curves will need to be developed. Radioisotope information will be integrated into BAT. The scientific principles behind these possibilities are being discussed in other papers at this NATO RTG-099 meeting, and when the data are sufficient they will be incorporated into AFRRI's software tools. This will be a fruitful area of research for years to come.

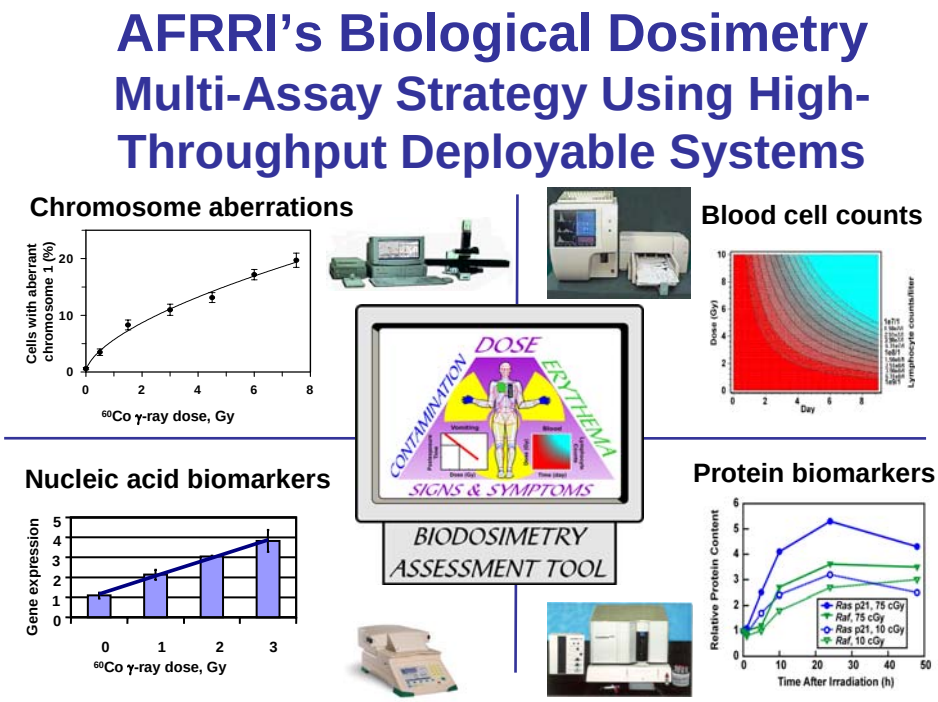

Figure 17: Biomarkers with potential for biodosimetry

4.0 CONCLUSIONS

- Dynamic recording of diagnostic information is essential to support the medical response to radiation-casualty incidents.
- AFRRI's current radiation biological dosimetry tools are available at AFRRI's website for downloading, and also through a CD-ROM to be available for distribution by the Department of Homeland Security's Emergency Response Technology Program.
- Future development will update these tools and expand them to additional types of devices. New tools based on emerging biomarkers will be developed.

5.0 ACKNOWLEDGEMENTS

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6.0 REFERENCES

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